K051838

Concentric Medical, Inc.
Modified Concentric Retriever

SEP - 1 2005

510(k) Summary

General Information

Classification	Class II, Percutaneous Catheter per 21 CFR § 870.1250
Trade Name	Modified Concentric Retriever
Submitter	Concentric Medical, Inc. 1380 Shorebird Way Mountain View, CA 94043 tel: 650-938-2100
Contact	Jean M. Caillouette, RAC Manager, Regulatory Affairs

Intended Use

The Modified Concentric Retriever is intended to remove foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vascular systems.

Predicate Device

Concentric Retriever LX K040745
Manufactured by Concentric Medical, Inc.

Device Description

The Modified Concentric Retriever consists of a flexible, tapered core wire with five cylindrically-shaped helical loops at the distal end. Polymer filaments are fastened to the helix to aid in the entrapment and retrieval of foreign bodies. A radiopaque coil is attached over the distal end to facilitate fluoroscopic visualization. The device is covered with a hydrophilic coating to reduce friction during use. A visible marker on the Retriever proximal end aids the physician in determining when the Retriever tip is about to exit the Microcatheter tip. The device is provided with an insertion tool to facilitate introduction into a Microcatheter and a torque device to facilitate manipulation. The Modified Concentric Retriever is delivered to the treatment site using a compatible Microcatheter as specified in the Instructions for Use.

Materials

All materials used in the manufacture of the Modified Concentric Retriever are suitable for the intended use of the device and have been used in numerous previously-cleared products.

Testing Summary

The Modified Concentric Retriever has successfully passed all performance and functional testing performed demonstrating that the device performs in accordance with the requirements of the Product Specification. The Modified Concentric Retriever has

been designed, developed and manufactured in accordance with the Concentric Quality System which complies with the requirements of Title 21, CFR§820.30.

Summary of Substantial Equivalence

All characteristics/attributes of the Modified Concentric Retriever are either identical or substantially equivalent to the existing, legally marketed predicate device identified in this application. As such, Concentric Medical, Inc. believes the Modified Concentric Retriever is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2005

Concentric Medical, Inc.
c/o Ms. Jean M. Caillouette
Manager, Regulatory Affairs
1380 Shorebird Way
Mountain View, CA 94043

Re: K051838
Modified Concentric Retriever, Model 90039
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: August 11, 2005
Received: August 12, 2005

Dear Ms. Caillouette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	This application K051838
Device Name:	Modified Concentric Retriever
Indications for Use:	The Modified Concentric Retriever is intended to remove foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vascular systems.

Prescription Use _X_ OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051838

Confidential